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10/728,033	12/04/2003	Stephen F. Badylak	3220-73985	8358

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EXAMINER	
SCHUBERG, LAURA J	
ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
04/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/728,033	BADYLAK, STEPHEN F.	
	Examiner	Art Unit	
	LAURA SCHUBERG	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to papers filed 12/19/2008.

Claim 1 has been amended and no claims have been newly added or canceled.

Claims 1-16 are currently pending.

Previous Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak (WO 98/25637) in view of Patel et al (US 5,955,110) and Oliver et al (US 4,399,123).

Amended claim 1 is drawn to a method for inducing the repair of damaged or diseased body wall tissues comprising the steps of preparing a graft composition comprising basement membrane of a warm-blooded vertebrate by removing endogenous cells, DNA and endotoxins from the graft and administering the graft to a patient in an amount effective to induce repair, wherein the body wall tissue comprises a multilaminate, stratified structure comprising different tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue and the serous lining of the body wall cavity, wherein the graft composition further comprises a glycoprotein.

Dependent claims include the site of repair, wherein the graft is multi-layered, thickness of the layers, format of the layers, administration type and form, sterilization of the graft, addition of growth factors, and seeding with exogenous cells.

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The preparation involves the removal of cells and cellular components from the liver tissue and this process will also remove DNA and endotoxins as well (page 3 lines 3-32). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce

repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet (patch) or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500 μ (page 17 line 14). Sterilization of the composition by peracetic acid is taught as most preferred (page 5 lines 20-28). The composition has a honeycomb-like structure (page 10 lines 24-25) and this is interpreted as perforated. The reference includes wherein growth factors and glycoproteins that facilitate cellular proliferation are added to the composition (page 11 lines 16-20) as well as the seeding with various exogenous cell types (page 12 lines 20-28).

Badylak ('637) does not specifically teach wherein the body wall tissue to be repaired comprises the abdominal wall or wherein the graft composition is formed as a multilayered homolaminate construct.

Oliver et al teach a method wherein basement membrane is used various branches of surgery for the treatment of hernias (column 1 lines 55-66 and column 5 lines 60-62).

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater

surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

In addition, Badylak ('637) teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, one of ordinary skill in the art would have been motivated to use the invention of Badylak ('637) for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation

(page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Oliver et al teach the use of basement membrane in hernia repair (column 5 lines 60-65).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badlak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, the combined teachings of Badylak, Patel and Oliver et al render obvious Applicant's invention as claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 7,482,025 in view of Patel et al (US 5,955,110) and Badylak (WO 98/25637) and Oliver et al (US 4,399,123).

Although the conflicting claims are not identical, they are not patentable distinct from each other because the patented claim is drawn to a method for inducing the formation of endogenous tissue at a site in need in a warm-blooded vertebrate comprising implanting a graft composition comprising gelled liver basement membrane tissue of a warm-blooded vertebrate at the site in need in an amount effective and further comprises a glycoprotein.

The '025 Patent does not include wherein the body wall or abdominal wall is the site of repair or wherein the construct is multilayered, the thickness of the layers or wherein the construct is formed as a homolaminate. Wherein the construct is in a sheet form and surgically implanted or in powder form is also not included.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500 μ (page 17 line 14). Badylak ('637) also teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had

been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28). The reference includes wherein growth factors and glycoproteins that facilitate cellular proliferation are added to the composition (page 11 lines 16-20).

Oliver et al teach a method wherein basement membrane is used various branches of surgery for the treatment of hernias (column 1 lines 55-66 and column 5 lines 60-62).

Therefore, one of ordinary skill in the art would have been motivated to use the method of the copending application for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing

cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badylak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. The use of different forms such as multilayered, powder and sheet would have been obvious to include in the copending application because Badylak and Patel teach that these are suitable forms for the construct. The thickness of the layers of the construct would have been a matter of routine optimization depending on the thickness of the body wall in need of repair. One of ordinary skill in the art would have had a reasonable expectation of success because

Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, the combined teachings of the patented claims and Badylak, Patel and Oliver et al render obvious Applicant's invention as claimed.

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 9 of U.S. Patent No. 6,793,939 in view of Patel et al (US 5,955,110) and Badylak (WO 98/25637) and Oliver et al (US 4,399,123). Although the conflicting claims are not identical, they are not patentable distinct from each other because the patent is drawn to a method for inducing the formation of endogenous tissue at a site in need in a warm-blooded vertebrate comprising implanting a graft composition comprising an extracellular matrix consisting essentially of basement membrane of liver tissue of a warm blooded vertebrate in an amount effective to induce endogenous tissue growth at the site of administration. Wherein the basement membrane is fluidized and administered by injection and administered by surgically implanting and wherein the liver tissue is in sheets having a thickness of up to about 500 μ are also included.

The claims of the patent do not include wherein the body wall or abdominal wall is the site of repair or wherein the construct is multilayered, or wherein the construct is formed as a homolaminate. Wherein the construct is in a sheet form and surgically implanted or in powder form is also not included.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500 μ (page 17 line 14). Badylak ('637) also teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation

(page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28). The reference includes wherein growth factors and glycoproteins that facilitate cellular proliferation are added to the composition (page 11 lines 16-20).

Oliver et al teach a method wherein basement membrane is used various branches of surgery for the treatment of hernias (column 1 lines 55-66 and column 5 lines 60-62).

Therefore, one of ordinary skill in the art would have been motivated to use the method of the patent for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and

biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badylak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. The use of different forms such as multilayered, powder and sheet would have been obvious to include in the copending application because Badylak and Patel teach that these are suitable forms for the construct. One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

One of ordinary skill in the art would have been motivated with a reasonable expectation of success in adding glycoproteins to the basement membrane composition as Badylak ('637) suggest that these facilitate cellular proliferation (page 11).

Therefore, the combined teachings of the patent claims and Badylak, Patel and Oliver et al render obvious Applicant's invention as claimed.

Response to Arguments

Applicant's arguments filed 12/19/2008 have been fully considered but they are not persuasive.

Applicant argues that because WO 98/25637, the '110 patent and the '123 patent do not provide any suggestion of the specific element of removing DNA from the graft composition, the references either alone or when combined are incapable of defeating the patentability of Applicant's claims 1-16 which require removal of DNA.

This is not found persuasive because the method described in WO 98/25637 includes the removal of cells and cellular components from the liver tissue and this process will also remove DNA as well (page 3 lines 3-32) as DNA is a component of cells. By removing cells, the practitioner also removes the DNA inherently present in the cells as well.

Applicant argues that the '123 patent teaches away from the claimed invention because it requires the removal of antigenic glycoproteins and the claimed invention requires the presence of glycoproteins. Applicant asserts that because of the teaching away of the '123 patent that it can not be properly combined with WO 98/25637.

This is not found persuasive because the WO 98/25637 teaches that proteins, including glycoproteins, that facilitate cellular proliferation can be added back into the

basement composition (page 11 lines 16-20). The '123 patent only suggests the removal of those glycoproteins that would cause an antigenic response, not that glycoproteins could not be added back in to the composition as suggested by WO 98/25637. Clearly many antigenic components (cells, glycoproteins, growth factors) are removed during the preparation of the basement membrane and then new components added back in a form more suitable for the intended method of repair.

Applicant argues that because of the complexity of body wall tissue, a skilled artisan would not have had a reasonable expectation of success to substitute liver basement membrane for the intestinal-derived graft composition in the '110 patent to repair body wall tissue.

This is not found persuasive because the '123 patent demonstrates that basement membranes are known in the art to be successfully used for the repair of the body wall such as in hernia repair. Badylack (WO 98/25637) also states that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa (page 1 lines 16-24) such as the repair method described in the '110 patent. Clearly one of ordinary skill in the art would have been motivated to practice the method of body wall repair with the basement membrane composition of WO 98/25637 with a reasonable expectation of success given these teachings.

Applicant argues that the graft compositions described in WO 98/25637 are not compositionally and structurally identical to those described in the '110 patent. Applicant asserts that it is accordingly not obvious that the liver-derived graft composition

described in WO 98/25637 could be substituted for the compositions described in the '110 patent and could be used effectively for *in vivo* repair of a complex structure such as a body wall. Applicant asserts that Applicant's statement (from WO 98/25637) that liver basement membrane "can be substituted for intestinal submucosa tissue in most, if not all, of the applications previously reported for intestinal submucosa, including enhanced wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation" refer to general effects of liver basement membrane graft compositions. Applicant asserts that these statements do not mean that because liver basement membrane compositions cause growth-promoting effects it is obvious that they would be effective in repairing *in vivo* the complex structure of Applicant's amended claims 1-16.

This is not found persuasive because Patel (the '110 patent) specifically teaches that the submucosal tissue, suitable for use in the graft constructs used for repair of the abdominal body wall, comprises naturally associated extracellular matrix proteins, glycoproteins and other factors and that one source of this tissue is small intestinal tissue (column 3 lines 25-27). Clearly other types of tissue that are similar in structure and composition are to be considered as suitable as well. In addition, the WO document (WO 98/25637) teaches that the liver basement membrane construct can be further manipulated to suit various medical applications (page 9 lines 10-11), including *in vivo* repair (page 12 line 14). The WO document also reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal

tissue (page 1 lines 15-20). Clearly it is not required that liver basement membrane be compositionally and structurally identical to those tissue compositions described in the '110 patent for it to be considered as a suitable substitute.

Applicant's arguments with regard to the double patenting rejections are identical to those presented above and are therefore also not found persuasive as well.

Therefore the claims remain rejected as above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Laura Schuberg